REMARKS

This Response is submitted in reply to the non-final Office Action mailed on February 5, 2009. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 115808-510 on the account statement.

Claims 29-32 and 35-56 are pending in the application. Claims 1-22 and 33 were previously canceled. In the Office Action, Claims 29-32 and 34-56 are rejected under 35 U.S.C. §112 and under 35 U.S.C. §103(a). In response, Applicants amend Claims 30, 38, 40, and 46 and cancel Claims 41 and 47. The amendments do not add new matter and are supported in Applicants' specification at page 9, lines 21-30. In view of the amendments and for at least the reasons set forth below, Applicants respectfully submit that the §112 and §103 rejections of Claims 29-32 and 35-56 should be withdrawn.

In the Office Action, Claims 29-32 and 34-56 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that the previous amendment to independent Claims 29 and 39 is not found in the instant disclosure, particularly that at least pancreatic extract is needed in the composition. The Office Action also asserts that Applicants' specification only provides support for a pancreatic function promoter that can be either pancreatic extract, or lipase or a gut modifier. Applicants respectfully disagree. Applicants' specification states that the pancreatic function promoters that can be used in this invention include, for example, gut pH modifiers, pancreatic extracts, and combinations thereof. See, specification, page 9, lines 5-6. Therefore, the specification provides clear support for a composition that comprises a pancreatic function promoter that includes at least a pancreatic extract because the pancreatic function promoter can also include, for example, gut pH modifiers.

Accordingly, Applicants respectfully submit that the claims as presented comply with the written description requirement under 35 U.S.C. §112, first paragraph.

In the Office Action, Claims 29-32 and 34-56 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically regarding independent Claims 29 and 39, the Office Action asserts that the pet animal's condition is unclear, the correlation

between lipid assimilation and intestinal mucosa function is unclear, and the type of pancreatic extract referred to is unclear. Applicants respectfully disagree.

Under 35 U.S.C. §112, second paragraph, the claims must meet two requirements: (a) the claims must set forth the subject matter that Applicants regard as their invention and (b) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. Under MPEP 2172, the invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which Applicants regard as their invention. Evidence to the contrary includes, for example, contentions or admissions contained in briefs of remarks filed by Applicants. See, *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 55 USPQ2d 1279 (Fed. Cir. 2000). Evidence to the contrary, however, does not include Applicants' specification. Applicants submit, therefore, that the subject matter set forth in the claims is the subject matter that Applicants regard as the invention and that no evidence exists to the contrary.

Regarding requirement (b), Applicants submit that the claims particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. Specifically, independent Claims 29 and 39 apprise one skilled in the art of the scope of those claims. Claim 29, for example, is a method claim for imparting at least one benefit, wherein the method includes a single method step, that being the step of administering to a pet a composition comprising two promoters, one being a pancreatic function promoter, and the other being either a liver function promoter or an intestinal function promoter. Claim 39 recites a regimen comprising a single dietary component. That component, similar to Claim 29, comprises two promoters, one being a pancreatic function promoter, and the other being either a liver function promoter or an intestinal function promoter. Applicants submit that one having skill in the art would be sufficiently apprised of the scope of these claims, and would understand the metes and bounds of these claims, given that Claim 29 recites a one-step method and Claim 39 recites a regimen comprising a two-part dietary component.

The Office Action also asserts that Claims 30, 38, 40, 41, 43, 46, 47 and 50 fail to define sufficient metes and bounds and that Claim 45 is indefinite for reciting proteases having the capacity to promote the formation of lipoproteins even though proteases generally function to break down proteins. In response, Applicants amend Claim 30 to recite a gut pH modifier

selected from the group consisting of an acidifier, an alkalanizer, a buffer, a prebiotic and a probiotic microorganism. Claim 38 has also been amended to recite a method according to claim 29 wherein the outward appearance is observable in any one or more of: improved body condition; improved muscle tone; and improved skin and coat condition. Claim 46 has been amended to replace "an anti-inflammatory agent" with "an omega-3 fatty acid." Regarding Claim 45, Applicants submit that the Office Action is incorrect. Claim 45 does not recite proteases having the capacity to form lipoproteins. Rather than recite proteases that directly form lipoproteins, Claim 45 recites proteases having the capacity to promote the formation of lipoproteins. Therefore, Claim 45 does not conflict with what the Office Action asserts as the generally function of proteases.

Based on the amendments and for at least the reasons recited above, Applicants submit that the present claims are sufficiently definite as required by 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejections of Claims 29-32 and 34-56 under 35 U.S.C. §112, first and second paragraphs, be withdrawn.

In the Office Action, Claims 29-32 and 34-56 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,471,999 to Couzy, et al. ("*Couzy*") in view of U.S. Patent No. 5,290,571 to Bounous, et al. ("*Bounous I*") or U.S. Patent No. 5,451,412 to Bounous, et al. ("*Bounous II*") and further in view of Simpson, et al. (Micronutrient Status in Patients with Gastrointestinal Disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001) ("*Simpson*"), Suzuki, et al. (Effects of Bacterial or Porcine Lipase with Low- or High-Fat Diets on Nutrient Absorption in Pancreatic-Insufficient Dogs. Gastroenterology 1999; 116:431-437 7) ("*Suzuki*") and WO 01/62280 to Margolin, et al. ("*Margolin*"). Independent Claims 29, 39, 54 and 55 recite, in part, a composition, component or diet comprising a pancreatic function promoter comprising at least a pancreatic extract and a promoter selected from the group consisting of a liver function promoter and an intestinal mucosa function-promoter. Applicants respectfully submit that the cited references, alone or in combination, fail to disclose or suggest every element of the present claims.

Couzy fails to disclose or suggest a composition, component or diet comprising a pancreatic function promoter comprising at least a pancreatic extract and a promoter selected from the group consisting of a liver function promoter and an intestinal mucosa function-

promoter as required, in part, by independent Claims 29, 39, 54 and 55. The Office Action asserts that *Couzy* teaches a pancreatic function promoter by teaching use of lipase. See, Office Action, page 7, lines 15-17. Applicants respectfully disagree and submit that the word "lipase" does not appear to be taught or suggested anywhere in *Couzy*. Though *Couzy* teaches use of "lactase," lactase is different from lipase, as lipase generally is considered a water-soluble enzyme that catalyzes the hydrolysis of ester bonds in water–insoluble lipid substrates, while lactase is generally considered a glycoside hydrolase involved in the hydrolysis of the disaccharide lactose into constituent galactose and glucose monomers.

In response, the Office Action asserts that Applicants lack sufficient disclosure for the limitation "a pancreatic function promoter comprising at least a pancreatic extract." Applicants disagree for the reasons discussed above in response to the Office Action's §112, first paragraph rejection. Specifically, Applicants' specification states that the pancreatic function promoters that can be used in this invention include, for example, gut pH modifiers, pancreatic extracts, and combinations thereof. See, specification, page 9, lines 5-6. Therefore, the specification provides clear support for a composition that comprises a pancreatic function promoter that includes at least a pancreatic extract because the pancreatic function promoter can also include, for example, gut pH modifiers. The Office Action also asserts that *Couzy* teaches use of lipase. However, as discussed above, lipase does not appear disclosed or suggested in *Couzy*.

Applicants submit that the secondary references do not remedy the deficiencies of *Couzy*. The Office Action relies on *Bounous I* and *II* arguably to teach a whey protein-containing composition that promotes glutathione (liver function promoter) and soy lecithin (liver function promoter). See, Office Action, page 9, lines 10-17. However, both these references still fail to teach or suggest use of a pancreatic function promoter. The Office Action relies upon *Simpson* arguably to disclose lipid assimilation and how it can cause other nutritional deficiencies. Similarly, the Office Action relies on *Margolin* arguably to disclose lipid assimilation capacity with vitamin E absorption. Therefore, like *Bounous I* and *II*, *Simpson* and *Margolin* fail to remedy the deficiencies of primary reference *Couzy*.

Finally, *Suzuki* is also deficient. Though the Office Action asserts that *Suzuki* teaches lipase (see, Office Action, page 9, lines 17-18), the present claims do not recite use of lipase, specifically the bacterial and porcine lipase taught in *Suzuki*. Instead, independent Claims 29,

39, 54 and 55 recite use of a pancreatic extract, not the bacterial or porcine lipase of *Suzuki*. Moreover, Applicants have amended dependent Claims 30 and 40 to remove the claim term "lipase." Therefore, *Suzuki's* teaching of a non-pancreatic lipase fails to remedy the deficiencies of primary reference *Couzy*.

In the Office Action, Claims 29-32 and 34-56 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/15719 to Fuchs, et al. ("*Fuchs*") in view of *Bounous I* or *Bounous II* and further in view of *Simpson*, *Suzuki* and *Margolin*. Applicants submit that the cited references, alone or in combination, fail to disclose or suggest a composition, component or diet comprising a pancreatic function promoter comprising at least a pancreatic extract and a promoter selected from the group consisting of a liver function promoter and an intestinal mucosa function-promoter as required, in part, by independent Claim 29, 39, 54 and 55.

The Office Action asserts, however, that *Fuchs* discloses use of lipase. See, Office Action, page 12, lines 16-18. Applicants disagree and submit that the term "lipase" does not appear to be taught or suggested anywhere in *Fuchs*. Applicants also note that "pancreas" does not appear anywhere in *Fuchs*. Therefore, contrary to the Office Action's assertions, *Fuchs* fails to disclose or suggest a pancreatic function promoter comprising at least a pancreatic extract as required by the claims. Applicants further submit that the secondary references fail to remedy the deficiencies of primary reference *Fuchs*.

As stated previously, the Office Action relies on *Bounous I* and *II* arguably to teach a whey protein-containing composition that promotes glutathione (liver function promoter) and soy lecithin (liver function promoter). See, Office Action, page 11, lines 11-19. However, both these references also fail to teach or suggest use of a pancreatic function promoter. The Office Action relies upon *Simpson* arguably to disclose lipid assimilation and how it can cause other nutritional deficiencies. Similarly, the Office Action relies on *Margolin* arguably to disclose lipid assimilation capacity with vitamin E absorption. Therefore, like *Bounous I* and *II*, *Simpson* and *Margolin* fail to remedy the deficiencies of primary reference *Fuchs*.

Finally, *Suzuki* is also deficient. Though the Office Action asserts that *Suzuki* teaches lipase (see, Office Action, page 12, lines 18-20), the present claims do not recite use of lipase, specifically the bacterial and porcine lipase taught in *Suzuki*. Instead, independent Claims 29, 39, 54 and 55 recite use of a pancreatic extract, not the bacterial or porcine lipase of *Suzuki*.

Moreover, Applicants have amended dependent Claims 30 and 40 to remove the claim term "lipase." Therefore, *Suzuki's* teaching of a non-pancreatic lipase fails to remedy the deficiencies of primary reference *Fuchs*.

Therefore, Applicants respectfully submit that the cited references, alone or in combination, fail to disclose or suggest every element of the present claims. Accordingly, Applicants respectfully request that the obviousness rejections of Claims 29-32 and 34-56 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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